

REMARKS-General

1. The currently amended independent claim 51 and the newly drafted claim 82 incorporates all structural limitations of the original claim 1 and includes further limitations previously brought forth in the disclosure. No new matter has been included. All claims 51-60, 65-69, 74-81, 82-104 are submitted to be of sufficient clarity and detail to enable a person of average skill in the art to make and use the instant invention, so as to be pursuant to 35 USC 112.

2. With regard to the rejection of record based on prior art, Applicant will advance arguments to illustrate the manner in which the invention defined by the newly introduced claims is patentably distinguishable from the prior art of record. Reconsideration of the present application is requested.

Response to Rejection of Claims 51-73 under 35USC112

3. The applicant submits that the currently amended claims 51 and 78-81 particularly point out and distinctly claim the subject matter of the instant invention, as pursuant to 35USC112. Therefore, all claims 51, 78-81, 51-60, 65-69, 74-81, 82-104 particularly point out and distinctly claim the subject matter of the instant invention, as pursuant to 35USC112. No new matter is included.

Response to Rejection of Claims 51-73 under 35USC103

4. The Examiner rejected claims 53, 54, 57-60, 65, 67, 74, 76 over Jiang et al. (O or U, CN1393264) and Song et al. (V) in view of Nishimura et al. (R), and further in view of Ebrup et al. (O) Gorogawa et al. (W) and Hamaoka et al (X). Pursuant to 35 U.S.C. 103.

5. The Examiner rejected claims 51, 52-56, 66, 68, 69, 74-77 over Jiang et al. (O or U, CN1393264), Song et al. (V) and Nishimura et al. (R), in view of Yoshikawa et al. (U1), and further in view of Ebrup et al. (O) Gorogawa et al. (W) and Hamaoka et al (X). Pursuant to 35 U.S.C. 103(a).

6. The Examiner rejected claims 51, 53, 54, 57-60, 65, 67, 74 and 76 over Song et al. (V), Lee et al. (V) and Nishimura et al. (R), in view of Gorogawa et al. (W) and Hamaoka et al (X).

7. The applicant respectfully submits that the present invention is to make use of natural herbs for treating a living object with non-insulin dependent diabetes. As stated in the objective, the approach of the present invention includes providing combination effect of sulfonylurea and biguanides (page 8, paragraph 2), making use of Berberine taking into consideration of the lethal dose of Berberine (page 6, paragraph 3). As indicated in the background, the problem of painful injection of insulin and the side effects of synthetic medicine are problems to be solved by the present invention. **Therefore, the use of insulin and any reliance on insulin is in a completely different direction with respect to the present invention.**

8. In Jiang et al. (O or U, CN1393264), the spirits or approach has never been departed from the use of insulin. In the section "Details of Invention", all experiments and combination of compositions have demonstrated the results of using Berberine together with Insulin to achieve the desire effect. Even though in the disclosure there is a wild variety of possibilities being mentioned, **the further provisions of desire results ONLY emphasizing on the combination use of insulin to support the variety of possibilities, has in fact, negate the direction to 'using Berberine together with insulin' for the desired results.** There is no ground for all the wild variety of possibilities as stated in Jiang et al. (O or U, CN1393264). It is doubtful whether Jiang et al. (O or U, CN1393261) can be relied upon for the wild varieties of possibilities, or be given any weight on it. It is also doubtful whether Jiang et al. (O or U, CN1393264) can be relied upon for supporting independent use of Berberine without insulin, given that fact that Berberine is deemed to be an uncommon herb because of difficulties in finding a range of dosage. Furthermore, the independent use of Berberine without insulin, based on successful data on its combination use with insulin without any hints or actual data for prospect of success for the independent use of Berberine, will merely negate the direction to 'using Berberine together with insulin' for the desired results.

9. The applicant objects to the use of an outrageous number of cited arts as the ground of objections under 103. In view of the number of cited arts, in addition to the number of different foreign languages such as Chinese, Korean and Japanese involved, and the number of countries such as China, Korea, Japan, Netherlands, and India involved, the hypothetical person under 103 should be a person with GENERAL

skills in the art, but not a person who is highly knowledgeable, highly multi-nationals with multi-languages skills.

10. The applicant also restated that a mere recitation of possible therapeutic effect does not in any way anticipate or suggest any composition for treating living object with non-insulin dependent diabetes mellitus ***through restoration of insulin beta cells***. Experiments have shown a promising effect of restoring insulin beta cells by administering berberine and catalpol. This is an ***unexpected result*** from combining the two active ingredients. The results as demonstrated in Example 13 in relation to the seven indexes, that is: (1) fasting plasma sugar level before and after treatment (FPG), (2) Apolipoprotein AI (APOAI), (3) Apolipoprotein B (APOB), (4) total cholesterol (TC), (5) Triglyceride (TG), (6) High density lipoprotein (HDL), and (7) Low density lipoprotein (LDL) has further support the unexpected results which is only achieved by the subject matter of the present invention. Neither Jiang nor Song and the related cited arts in any way teach, suggest or motivate the use of the two claimed active ingredients for lowering blood glucose level and risk of complications through restoration of insulin beta cells in living objects such as mice.

11. The applicant further restated that Jiang et al. merely teaches the use of berberine as an additional composition for use with insulin in which the object is to boost up the effect of insulin. The use of insulin is contradictory to the rationale of using the composition and is in a way teaches away from the present invention. Song et al. merely provides research data of berberine and is silent on its application or combination effect with other composition. There is no indication of its application or combination effect with Catapol which is the second active ingredient of the present invention. While Jiang et al. teaches away from the present invention, Song et al. is insufficient in having any implication to the present invention, the prima facie case of obviousness is not fully demonstrated by Jiang et al and Song et al. in view of other references.

Combination of Elements

12. The Court of Appeal of the Federal Circuit has stated, “[V]irtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983). Thus,

“[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 5 USPQ 2d 1600 (Fed. Cir. 1988).

13. In other words, the Office Action cannot, based on hindsight gained from the applicant's invention, argue that it is obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The obviousness cannot be shown by combining the teachings of the prior art unless there is some teaching or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984); *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278 (Fed. Cir. 1987).

14. The Federal Circuit in *In re Dembiczak*, 175 F.3rd 994, 50 USPQ2d 1614 (Fed. Cir. 1987) deprecated rejections based upon “a hindsight-based obviousness analysis” and emphasized that what is required is a “rigorous application of the requirement for a showing must be clear and particular” and that broad conclusory statements regarding the teaching of multiple references and “a mere discussion of the ways that the multiple prior art references can be combined to read on the claimed invention” is inadequate. Absent an explicit suggestion or teaching of the combination in the prior art references, there must be “specific....findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis”.

15. In addition, were a claimed relationship between variables or parameters is not discussed or suggested by a prior art reference, such reference cannot render such relationship of variables obvious unless such variables are inherent. See *In re Rejckaert*, 9F.3d 1531 (Fed. Cir. 1993) (“the Commissioner points out that in the recording art, the exact matching of signal time to recording time is an optimal condition, and that this condition would be met by fulfilling the claimed relationship. While the condition described may be an optimal one, it is not ‘inherent’ in Awamoto. Nor are there means to achieve this optimal condition disclosed by Awamoto, explicitly or implicitly.”)

16. Indeed, the only mention of relationship and percentage of all the combining elements to form the composition as claimed is in applicants own specification and claims. Accordingly, it appears that the Examiner has fallen victim to the insidious effect of a hindsight analysis syndrome where that which only the inventor taught is used against the teacher in W.L. Gore and Associates v. Garlock, Inc., 220 USPQ 303, 312-313 (Fed. Cir. 1983) cert. denied, 469 U.S. 851 (1984).

17. In view of the argument set forth in the previous amendments and the above, the applicant believes that for all of the foregoing reasons, all of the claims are in condition for allowance and such action is respectfully requested.

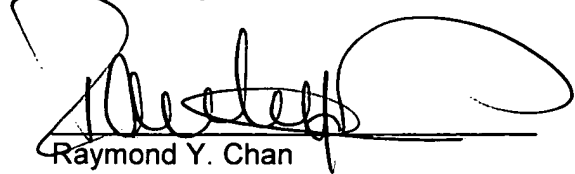
The Cited but Non-Applied References

18. The cited but not relied upon references have been studied and are greatly appreciated, but are deemed to be less relevant than the relied upon references.

19. In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the rejection are requested. Allowance of claims 51-60, 65-69, 74-81, 82-104 at an early date is solicited.

20. Should the examiner believe that anything further is needed in order to place the application in condition for allowance, he is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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